EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

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Dossier requirements for centrally authorised products (CAPs)

Submission of applications to the European Medicines Agency, Members of the Committee for Medicinal Products for Human use (CHMP), Pharmacovigilance Risk Assessment Committee (PRAC) and Committee for Advanced Therapies (CAT)*

Application / Submission Type	Dossier Requirements for EMA, (Co-)Rapporteurs and Members/Alternates
Full application Extension Renewal Type IB variation (with PRAC involvement). Grouping or Worksharing containing NAPs[1]	All **eCTD format** submission for **Centrally Authorised products** sent to EMA via eSubmission Gateway/Web Client **will be considered delivered to all National Competent Authorities' representatives, alternates and scientific experts**. **Do not submit** any additional copies of eCTD format CAP submissions **directly to the NCAs** on CD/DVD or via CESP as this might lead to validation issues and cause delays. All Centralised Procedure submissions should be made via EMA eSubmission Gateway/Web Client only.

[1] Nationally authorised products concerned by this procedure should follow the dossier requirements as detailed here.

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Application / Submission Type	Dossier Requirements for EMA, (Co-)Rapporteurs and Members/Alternates
Type II variation (with or without PRAC involvement) Grouping or Worksharing containing NAPs1[1] Periodic Safety Update Report (PSUR)[2] Post Authorisation Safety Studies (PASS) Post-Authorisation Measures (PAMs) Annual Re-Assessment Article 20 procedure	**CAT members nominated by the European Commission not linked to EMA Common Repository:** 1 eCTD version after EMA technical validation (or by start of the content/regulatory validation phase) and after Validation Supplementary Information CAT* submissions are only required if the product is an advanced therapy (AT).
Type IA or IB variation Transfer Art 61(3) Notification Art. 58 (WHO) submissions Active Substance Master File (ASMF) Plasma Master File (PMF)	As above Note: ***No CAT* or PRAC submissions required for these procedure types.***

For any other procedure type, such as Referrals submissions, PASS 107, workshare, Signal Detection and Ancillary Medical devices submissions and non eCTD ASMFs please review the
Submission requirements for Referrals, ASMFs and Nationally authorised products.

*** for CAT, the dossier is only required by its members if the product is an advanced therapy (AT).**

[2] Nationally authorised products concerned by this procedure should follow the dossier requirements as detailed here

Names and Dossier delivery address for CAT members nominated by the European Commission – submission only required if the product is an advanced therapy (AT)

Name	Dossier Delivery Address
CAT Representatives of Healthcare Professionals:	**Only required if the product is an advanced therapy (AT)**
Member: Pieter Doevendans	European Society of Cardiology (ESCARDIO) Care of: University Medical Centre Utrecht Division Heart and Lungs Department of Cardiology, E 03.511 PO Box 85500 3508 GA UTRECHT The Netherlands
Alternate: Esteve Trias-Adroher	European Association of Tissue Banks (EATB) Care of: Parc Sanitari Sant Joan De Deu Carrer/Dr Antoni Pujadas, 42, Edifi Clínica Pujadas 08830 Sant Boi de Llobregat Spain
Member: Bernd Gänsbacher	Europastrasse 18 39058 Sarnthein Prov. Bozen Italy
Alternate: Ramadan Jashari	European Homograft Bank (EHB) Hôpital St. Jean – Site Méridien Rue du Méridien 100 1210 Brussels Belgium

CAT Representatives of Patient Organisations:	Only required if the product is an advanced therapy (AT)
Member: Kieran Breen	European Parkinson's Disease Association (EPDA) 1, Cobden Road, Sevenoaks, Kent, TN13 3UB United Kingdom
Alternate: Michele Lipucci di Paola	European Association for Rare Diseases (EURORDIS) Care of: Via N. Badaloni, 35 56122 Pisa Italy
Member: Mariette Driessens	European Genetic Alliances Network (EGAN) Koninginnelaan 23 3762 DA Soest The Netherlands
Alternate: Erik Briers	Isabellastraat 17 B-3500 Hasselt BELGIUM